EXHIBIT

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IN THE UNITED STATES DISTRICT COURT
OF THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	)	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO THE FOLLOWING CASES IN WAVE 1 OF MDL 200:	)	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
DONNA HANKINS, ET AL., Plaintiffs, vs. ETHICON, INC., ET AL. Defendants.	)	Civil Action No. 2:12-cv-01011

This is the Deposition of VLADIMIR IAKOVLEV, M.D., taken at the Hilton Hotel, 145 Richmond Street West, Toronto, Ontario, Canada, on Wednesday, the 9th day of March, 2016, commencing at 5:30 p.m.

REPORTED BY: JUDITH M. CAPUTO, RPR, CSR, CRR

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A P P E A R A N C E S:

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-- Upon commencing at 5:30 p.m.

EXHIBIT NO. 1: Clinico-Pathological Report of Dr. Vladimir Iakovlev Re: Donna Hankins dated January 24, 2016.
EXHIBIT NO. 2: Porter Adventist Hospital Surgical Pathology Consult Report Re: Donna Hankins dated November 16, 2011.
EXHIBIT NO. 3: Flash Drive Containing Files Reviewed by Dr. Iakovlev in Compiling his Clinico-Pathological Report Re: Donna Hankins.

VLADIMIR IAKOVLEV, M.D.,
called as a witness herein, having been first duly affirmed, testified on his oath as follows:

DIRECT EXAMINATION BY MR. COMBS:

Q. Dr. Iakovlev, I want to ask you some questions about Ms. Hankins' case.

In Ms. Hankins' case, she obviously has bladder cancer. You're not going to testify at the trial that her bladder was caused by her TVT

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implant, are you?

A. No.

MR. ANDERSON: Objection as to what he will testify to at trial, as I have done in the past. However, with that objection, what opinions are you going to offer with regard to whether or not the TVT caused her bladder cancer?

BY MR. COMBS:

Q. And when I look at page 11 of your report, you say that the two complications were independent clinically and morphologically.

Obviously, I'm not a physician, but what does that mean?

A. It means they're disconcurrent (ph). In fact, the cancer was caught really early and it was incidental discovery during the workup on the complications of the sling.

Q. So, I just wanted to make sure that I didn't have to ask you any questions as to whether you had an opinion that the TVT was in any way causal of the cancer, and it sounds like the answer is no?

A. Not to the degree I can connect.

Q. Thank you. Dr. Iakovlev, you did

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not prepare a synoptic report in this case. Did you count the nerves in this case?
A. Yes, we discussed it. I didn't because it doesn't change my opinions one way or the other.
Q. Did you grade the foreign body reaction in this case?
A. See with these findings, foreign body reaction is already abnormal. There is no point of grading it because it is more or less abnormal, but it's already abnormal. It doesn't really matter, abnormal here or abnormal there, it's abnormal.
Q. And is the answer you did not grade the foreign body reaction?
A. That is correct.
Q. And you did not find any damaged vessels or arteries in this case, did you?
MR. ANDERSON: Can he have his report, please?
THE WITNESS: Yes, that's what I was looking for.
MR. COMBS: Sorry.
MR. ANDERSON: That's all right.

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We have that as Exhibit 1?
THE WITNESS: Yes.
BY MR. COMBS:
Q. Okay.
A. Usually we have USB as Exhibit 1. Andy does as Exhibit 1. Anyway it doesn't matter.
MR. COMBS: I, in all these depositions have marked report 1, usually pathology 2, USB 3. I think you're right. From now on let's do the USB as 1. I think that is a better thing to do.
BY MR. COMBS:
Q. Okay. Let me have a look. First make sure that it's her report.
A. (Witness reviews document).
All right. So, as I recall, the question was regarding vascular damage.
Q. Yes, sir.
A. No.
Q. Dr. Iakovlev, you did not identify any traumatic neuromas in this case, did you?
A. No.
Q. And you made no findings that neural ganglia were involved with any of the slides, did you?

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A. (Witness reviews document).
No.
Q. No findings that any striated muscle was in the tissue sample that you inspected?
A. Yes, there was.
Q. And what slide was that?
A. Figure DH3.
Q. I just turned to it, okay.
Any other slides in which you found what you believe is striated muscle, other than DH3?
A. DH4.
Q. Any others?
A. No.
Q. Did you do a smooth muscle actin stain in this, on this specimen?
A. Most likely I did. Again, you have full list of stains and slides. Not here, not attached to the report, in the chain of custody form.
Q. Do any of the photographs that you've included in your report depict what you believe is smooth muscle?
A. Only if the finding is

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significant. So the significant finding for me for smooth muscle is I'm looking for parts of hollow organs being excised. Smooth muscle has to be in thick bundles, so it's corresponded to urethra, the bladder or the rectum, depending on the device.
Q. You did not find any "organs" in Ms. Hankins' tissue specimen, did you?
A. That is correct.
Q. Dr. Iakovlev, did you use any myeloperoxidase stains on Ms. Hankins' case?
A. No.
Q. Did you use any stains for PGP9.5 or for neurofilament?
A. No. I didn't use many other stains.
Q. I apologize, what?
A. I mean, there are more stains I did not use rather than I used.
Q. Okay. Any other stains that have been significant to your opinions in other cases that you did not use?
A. My standard set is H&E; sometimes the only stain is H&E. S100 and smooth muscle; again, smooth muscle and S100 are auxiliary stains.

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They are not primary stains, and they usually don't do anything else. Very rarely I do Von Kossa stain if I have some calcifications in the area. That's about it.

Q. Dr. Iakovlev, right before the deposition started, Mr. Anderson handed me a flash drive that we marked as Hankins Exhibit 3. It contains the medical records and a chain of custody form.

In addition to the specimen that you've reviewed in this case, would those materials constitute all of your case-specific materials for the Hankins case?

A. That is correct.

Dr. Iakovlev, earlier in the case we discussed reaching a stipulation on things like the next question so I think we'll be able to forego those. No depositions nor expert reports in the case?

MR. ANDERSON: Right. We'll stipulate that he -- I'm sorry.

MR. COMBS: That's okay.

MR. ANDERSON: We'll stipulate that in none of the Wave One cases did Dr. Iakovlev review

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any deposition transcripts, review any other expert reports from plaintiffs' experts, did not review -- did not speak with any of plaintiffs' treating doctors, was not present in the OR when the mesh was excised, was not part of the processing of the mesh at the hospital when the mesh was excised. Did not speak with or treat or examine the Plaintiff. That's all I can think of for now.

MR. COMBS: Okay, good. Thank you, Ben.

BY MR. COMBS:

Q. In regard to the specimen that you received from Porter Memorial Hospital, would that specimen have been handled with forceps prior to you receiving it?

A. Didn't we have a stipulation on that?

MR. COMBS: Let's go off the record for a second.

-- OFF THE RECORD DISCUSSION --

BY MR. COMBS:

Q. Prior to you receiving it, would the specimen have been handled by forceps?

A. Likely.

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Q. And dehydrated?

A. First fixed in formalin and then processed -- well, no.

Q. Do you want the pathology report?

A. Well, part of it. I received part of the specimen which was only preserved in formalin. And then they generated their own slides; that's when dehydration happened. But my specimen was dehydrated already at St. Michael's Hospital.

Q. I understand. So for the slide that they had prepared, they would have followed the normal -- to the best of your knowledge, would have followed the normal processing protocol?

A. That's correct.

Q. For the slide that St. Michael's prepared, they would have followed the protocol that you've told us about in other depositions?

A. Yeah, it's a similar process. In both labs, they processed their own tissue, and I processed what I received.

Q. All of the slides prepared for Ms. Hankins' case would involve a specimen that would have been treated with formalin and would

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have been treated with xylene, wouldn't it?

MR. ANDERSON: Objection to the form. Go ahead.

A. That's correct.

Q. And as a result of the process, the Plaintiff's sample would have hardened, shrunk and changed shape to some degree?

MR. ANDERSON: Objection to the form.

THE WITNESS: That is correct.

BY MR. COMBS:

Q. Maybe another area that we will have some agreement on, I'm going to ask now about analytical chemistry.

I believe in the earlier deposition that we reached agreement that no analytical chemistry was performed on Ms. Hankins' sample?

A. That is correct.

Q. And the testing that you would have performed in this case would have been using your light microscope, a polarizing filter, and then the stains that were used; is that correct?

A. That's correct.

Q. No other testing?

A. That's correct.

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Q. Dr. Iakovlev, will you be rendering any opinion in this case that Ms. Hankins' mesh was cytotoxic?
A. I cannot rule it out. So if you ask my opinion, can it be cytotoxic? I can tell you, it can.
Q. And my question is, would you be issuing an opinion in this case that Ms. Hankins' mesh was in fact cytotoxic to her?
MR. ANDERSON: I think what he's saying is that if you were to ask him that, he's going to give you his opinion.
So that it kind of goes back to my earlier objection, the way we handled it the last deposition.
MR. COMBS: I interrupted you.
MR. ANDERSON: The way we handled it the last deposition was, he went through and said, if I'm asked, I would say that I can't rule it out.
So that's kind of the -- as you can tell, it doesn't say in his report. He doesn't talk about cytotoxicity.
BY MR. COMBS:
Q. In any of the photographs that are

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attached in your report, is there an area in which you believe cell death occurred as a result of cytotoxic properties in the mesh?
A. The action is around the fibers, so if we look at the high-power figures where the --
MR. ANDERSON: Tell him which figure you're looking at.
THE WITNESS: For example, DH5 on page 21.
BY MR. COMBS:
Q. Yes.
A. So there is action around the mesh fibers. There is foreign body reaction around it and we know through publications there is constant remodeling of tissue around the fibers.
So, some cells are dying, some cells are coming back and recruited again. There is cell turnover here.
If it occurs due to mesh, the cell turnover, to a degree, yes, it happens right in there, in that area. If it's a direct effect of the mesh on the cells, I cannot show it; I cannot determine.

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Q. Dr. Iakovlev, will you be issuing an opinion in this case that Ms. Hankins' mesh migrated?
MR. ANDERSON: Objection to the form. Go ahead.
THE WITNESS: Yes.
BY MR. COMBS:
Q. And what would your -- I interrupted you before you finished?
A. I just wanted to expand.
Q. Okay. That's what I was going to do next. So what would your opinion be in that regard?
A. As I stated before, all meshes migrate. I cannot determine the degree of migration unless I have landmarks. But all of them migrate -- microns, millimeters, centimeters; it's all different.
Q. Are there any landmarks in Ms. Hankins' case?
A. (Witness reviews document).
I don't have landmarks in the pictures. There was an erosion, so there was enough migration of the mesh through the mucosa to become eroded.

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Q. Are you able to rule out that Ms. Hankins' tissue was thinning as opposed to the mesh moving?
MR. ANDERSON: Objection. Form.
THE WITNESS: This is a question like theory of relativity. What is moving towards what?
Is it the thinning because mesh is pressing against it, or it's not thinning, just mesh goes right through it? I don't think anybody can answer that question.
But the fact is pretty simple. It becomes exposed through a structure which it was not previously. So relatively to each other, it changed the position.
BY MR. COMBS:
Q. At the time of her mesh erosion, Ms. Hankins' vaginal tissue was suffering atrophy, wasn't it?
MR. ANDERSON: Objection to form. Go ahead.
THE WITNESS: It's a given; every woman experiences some atrophy. It's a natural process. So for all of these women, everybody who is getting implant sooner or later will have atrophy.

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BY MR. COMBS:
Q. Ms. Hankins was postmenopausal, wasn't she?
A. If she wasn't, she will be. There is no --
MR. ANDERSON: Why don't you look --
THE WITNESS: I can see she was 50 at the time of -- I don't know if she was postmenopausal but that's perimenopausal age.
BY MR. COMBS:
Q. Do you know whether Ms. Hankins was receiving estrogen replacement therapy at the time of her explant?
A. Most of women have some form of replacement therapy or estrogen treatment, either topical or systemic.
Q. As a result of the de-estrogenization of her vaginal tissues, were Ms. Hankins' vaginal tissues thinning at the time of her explant?
A. As I said, all women will sooner or later have it. We can talk about any of these ladies who experienced these complications; they will all have some atrophy.

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Some will be treated for some period of time. And then some of them will not be treated for some period of time.
Q. Dr. Iakovlev, you will not be offering any opinion in this case that Ms. Hankins' sling was properly placed or improperly placed, will you?
A. No.
Q. Dr. Iakovlev, will you be offering any opinion in this case that Ms. Hankins suffered from a mesh-related infection?
A. The records indicated that -- records indicated there was mesh erosion, so any erosion, any exposure of foreign body through mucosa will become infected.
Q. Were any cultures ever taken of the erosion spot?
A. No. As far as I remember, no. Usually it's not required. So I don't expect it to be taken.
Q. Did any of Ms. Hankins' treating physicians ever make a finding that Ms. Hankins had suffered from a wound infection?
A. I don't remember now was it in the

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records or not. I'm not looking specifically because it's a given.
Q. As we sit here today, you cannot point us to any spot in the medical records where one of Ms. Hankins' treating physicians diagnosed her as suffering from a mesh-related infection, can you?
A. (Witness reviews document).
I don't see it in this summary, but I'm not focusing on that because all this follows the exposure site.
Q. Dr. Iakovlev, you will not be offering an opinion at this trial that you found loose particles from the TVT mesh in the specimen that you received from Ms. Hankins, will you?
MR. ANDERSON: Objection to the form of the question as to what he will testify to at trial.
You can testify as to whether or not you have any opinions as to whether or not there were any loose particles of TVT in this specimen that you received from Ms. Hankins.
THE WITNESS: No, I did not see it. I did not see the particles.

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BY MR. COMBS:
Q. Dr. Iakovlev, I want to ask you some questions now about the photographs in your report. So let's start at DH1; what is that photograph?
A. This is the gross photograph of the specimen I received before the division.
Q. Is that the mesh that was removed from Ms. Hankins in 2011?
A. Yes, as far as I remember, November.
Q. Yes. The pathology report indicates November 14, 2011?
A. Yes, November 14th.
Q. Dr. Iakovlev, do you believe cautery was used to remove Ms. Hankins' mesh?
A. From just looking at these pieces, if it was used it was really gentle. I don't see much of cautery artifact except for maybe a couple of spots. Again, it may not be -- it's easier to appreciate microscopically. I think there was some cautery used.
Q. What photograph are you pointing to, please?

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A. DH2. It's hard to say exactly -- is it drying on the surface or cautery? It could be cautery.
Q. And where were you pointing to when --
A. This dark discoloration of the very tip of the tissue.
Q. Can you circle that for me?
MR. ANDERSON: He did.
BY MR. COMBS:
Q. And just put an "A" to the side of that. Thank you very much.
A. (Witness complies).
Q. Anywhere else in the photographs that you think represents a cautery artifact?
MR. ANDERSON: Just to clarify the record, he said it may.
MR. COMBS: Yeah. I apologize. I'm not trying to put words in your mouth. Anyplace else in the photographs that you think may represent a cautery artifact?
THE WITNESS: Actually, the more I look at it, the more I believe it is not cautery but more drying.

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BY MR. COMBS:
Q. Okay.
A. But usually that is, it is -- the extent of cautery changes in the tissue. Temperature drops really fast within 150 to 100 microns, goes to body temperature.
Q. Dr. Iakovlev, I'm going to ask you now about DH2; what is your opinion regarding the photograph at DH2?
A. So this would be a lower power view of the excised mesh. And you can see clearly that some of the fibers or cross-sections of the fibers still remain, and you can see them blue, which would correlate with the blue fibers on the previous image, DH1. And also correlates with the Gynecare type of products.
Other empty spaces are representing mesh fibers as well. Some of them are clear; that's why we don't see them. Some of them are floated away. But overall we can appreciate the mesh with some pores.
So these larger spaces in between pores, in between mesh fibers, are pores and they are filled with scar tissue. So this is the

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phenomenon which we call bridging fibrosis.
And then if we look around the clusters of the mesh fibers where there is like a knot or crossing of the mesh fibers in the knitting pattern, scar tissue extends beyond it.
So this would be scar encapsulation, together with bridging fibrosis or scarring within the pores, the encapsulating scar, or scar which is outside, this all together forms a scar plate, or sort of composite structure, where the scar reinforces mesh, and mesh reinforces scar within, and they both reinforce each other and they become stiff; much stiffer than scar would be on its own and much stiffer than mesh would be on its own.
Also, in this photograph we can appreciate darker blue purple areas around the mesh fibers. This is the foreign body type inflammation, and this is all happening within the scar plate. And as you can see here, there's no normal tissue. All of this tissue around it is scarring. And there is no neoplastic process.
So just looking at this photograph and thinking of what is abnormal here, comparing with normal vaginal tissue or any other normal tissue,

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first abnormality is presence of the foreign body of the mesh, and second abnormality is pathological changes in reaction to the mesh.
So there is scar encapsulation, scar plate formation, fibrous bridging, foreign body reaction -- all of these changes are related to the mesh. And there is no other natural condition.
Q. Is there any tissue in the photograph at DH2 that you believe is normal non-scar tissue?
A. Not that I can appreciate from this power. Maybe if I go on high power somewhere on the periphery because at some point there is a transition into normal tissue which is outside of the scar plate. I mean, if I had the slide I would be able to examine it further.
Q. Okay. I guess that actually was my question. Is there a place here where you can show us the junction between what you claim is scar plate and normal tissue?
A. I would need slide itself. I mean, is it more towards normal tissue here? I'm not sure. I cannot tell you.
MR. ANDERSON: You're pointing to the

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edge of it?
THE WITNESS: Edge, upper left corner.
BY MR. COMBS:
Q. Okay. Right in the center there's the empty space. Do you see what I'm referring to?
A. Yes.
Q. Exactly. Is that a pore?
A. No.
Q. What is that?
A. It's not a pore. It's a mesh fiber curling around in a knot or in a knitting pattern.
Q. And is that what you have drawn in yellow below that?
A. Yes.
Q. And how many microns is that space across?
A. Which space?
Q. The one we're talking about right now, the one that you have drawn the curling fiber in?
A. You would have to give me two points. If you point from which point to which point, then I can...

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Q. Yeah.
A. But just for the record, this space you just marked does not represent the pore, does not represent the single fiber.
What you just pointed to is an oval shape which is produced by a curved fiber, polypropylene fiber, which is being knitted around where the fibers are being knitted around each other. So it's a loop of mesh fiber.
Q. Okay.
A. It is not a pore; it is not a single fiber. It is a loop.
Q. And what would the measurements be of that pore on the A and the B axis?
MR. ANDERSON: It's not a pore.
BY MR. COMBS:
Q. Whatever you want to describe that as.
MR. ANDERSON: He's already described it. We have to make sure the record is clear here. That is not a pore, as he said, it is a knitted bundle of fibers.
BY MR. COMBS:
Q. Whatever you want to describe it

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as. All I want to know is, what are the measurements.
A. That's an estimate, around 600 microns, .6 millimeter from, I guess -- can I draw it here?
Q. Yes, sir.
A. So this distance is estimated, .6-millimeter.
Q. And the other distance?
A. The other distance will be somewhat larger, more or less 1 millimeter.
MR. ANDERSON: If it's more or less, put that on there. Or if it's approximations you need to let them know.
BY MR. COMBS:
Q. Dr. Iakovlev, I want to ask you now about the photograph at DH3.
A. Yes.
Q. And the legend for that photograph says:
"Partially scarred striated muscle, H&E, magnification equivalent to 2.5x objective. Scar is highlighted by orange color in

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the lower image copy."
Let me start by asking you -- the orange at the bottom, how was that added to the photograph?
A. I did it in the computer program.
Q. I don't understand what that means. Did you add it in manually in the computer program?
A. Yes, with my hand, just selected the areas and changed the color.
Q. Okay.
A. Instead of putting scar, scar, scar all over the image, how I did in other areas, I selected the scar tissue and changed the color for demonstration purposes.
Q. And would you agree that Ms. Hankins' tissue was not normal by virtue of the fact that she had stress urinary incontinence and pelvic organ prolapse?
MR. ANDERSON: Objection to form. Go ahead.
THE WITNESS: I don't understand. Are you implying that she had some genetic disorder that caused her to -- or something else?

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BY MR. COMBS:
Q. Let's start with that. Do you know what it was about her tissue that caused Ms. Hankins to have stress urinary incontinence and to have pelvic organ prolapse?
A. In many cases there is no abnormality to the tissue. It's age-related, a large baby during the birth, multiple birth, multiple factors. I mean, it's pretty common within women.
In some cases, there is some connective tissue disorder, but, I mean, from what I could see in the history, there was no description of a connective -- or collagen diseases.
Q. And so my original question was, by virtue of the fact that Ms. Hankins has had stress urinary incontinence and has had pelvic organ prolapse, do you define her tissue as being quote "normal" close quote?
MR. ANDERSON: Objection to form. Go ahead.
THE WITNESS: As I said, I mean, it's a very common condition. There are multiple factors; some of them are just large babies. Trauma during

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birth.
Histologically, I did not see anything abnormal. I would suspect there was exactly the same reaction to the mesh and pretty strong scar formation in the histological images. In histological sections, sorry.
BY MR. COMBS:
Q. Let's turn to DH4 now. Does DH4 represent any of the same area that you were testifying about in DH3, or is it a different area?
A. No, it is a different area. I think it's a different portion.
Q. Is anything substantially different about DH3 or DH4? Can we take the testimony that you gave us about DH3 as also being representative of DH4, or do we need to ask about it specifically as well?
A. Well, I don't think we talked too much about DH3. You asked me how I added the color but that was, I think, the extent of it.
Q. All right. What is it that you believe is significant about DH3?
A. This is the transition zone between scar tissue and partially scarred striated

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muscle. So that's how the striated muscle becomes attached.
Q. Where is the transition zone?
A. That's why I --
Q. Is it the border between the orange and the red?
A. So the -- it's like checkerboard. There's little bit of muscle here, little bit of scarring there, little bit of muscle; there is all this change. So anywhere beyond this line where I draw now, is just pure scar tissue, A.
And anywhere beyond this area which I'm marking now, is scar. And you can see that the scar -- striated muscle, B. So these areas are all interlaced, or there is integration of the atrophic muscle within the scar in all remaining zones.
Q. Anything else that would reflect your opinion about DH3?
A. Now, we know where the scar is coming from. And the scar is coming from the mesh, as we saw here in DH2.
So this mesh, which triggered bridging fibrosis and scar encapsulation and formed scar plate together with the scar, continues on and then

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continues on up to this point.
So entire mesh and scar plate within the mesh is being connected to the striated muscle here through these anchoring points. So now we are talking about muscle connected to the scar plate and scar plate connecting to the muscle.
So if muscle contracts it will produce pulling force on the entire scar plate. At the same time, since it is scarred, it cannot contract properly.
And, we know that scar contracts during maturation. So the striated muscle will be distorted and will be pulled, and will not be able to contract properly in the direction that it would contract physiologically.
Q. DH4?
A. DH4 is a similar example; however, it's much less organized. So the scarred muscle in this case is not as organized. This is just individual fibers within the scar tissue.
They will be contracting if there is stimulus for them if there was innervation preserved for them. And this is more of a transition zone between solid scar and partially

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viable muscle.
Q. And on the bottom, the part that you have marked in orange on the bottom picture on DH4, are any of the changes to that tissue caused by the fact that Ms. Hankins had tissue changes which caused her pelvic floor laxity? Or is it your testimony that all of those changes are related to the fact that there was a mesh implant?
A. I think we agreed that we did not agree that her tissue was the reason for pelvic organ prolapse.
But to answer your question, all these changes in this photograph are related to scarring, which is the result of mesh and mesh-associated tissue changes.
Q. Dr. Iakovlev, let me ask you now about DH5. And what is your opinion regarding that photograph?
A. So I can give you a summary, but it will not limit my opinions at trial if I'm asked questions.
DH5 is a higher magnification showing mesh fibers or cluster of mesh fibers surrounded by foreign body type inflammatory reaction.

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And outside of that halo of inflammatory reaction, there is scarring, or more permanent scar because tissue immediately around the mesh fibers is being remodeled.
There is action here. There are, as we talked about earlier, macrophages there. They are recruited to destroy the mesh fibers, try to degrade them. And at the same time, the damaged tissue. In this case, the tissue needs to be remodeled continuously.
But some distance away from it, the scar is more or less stable. So it's dense scar tissue outside of it.
Q. Is there normal tissue depicted on DH5?
A. No.
Q. So it will be your testimony that there is no normal tissue on DH5?
A. No. This is all abnormal. The presence of the foreign body, presence of foreign body reaction to it, and scarring is abnormal by definition.
All these components -- they are not present in normal vaginal tissue. And there is no

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neoplastic process, so there is no natural condition which could have occurred without the foreign body.
Q. Dr. Iakovlev, do you see the section in the upper left-hand corner of DH5 that is lighter?
A. Lighter? Yes, I do.
Q. Is it your opinion that that is scar tissue as well?
A. I cannot tell you from this cropping. I don't know what's beyond, because sometimes lightness is caused by tissue separation during processing. Like if we see here, there is some lightening, but just beyond it there is scar again.
So this lightening can be just a zone of rarefaction of the tissue, due to artifacts. And then there is continuation of scar plate further down. I don't know; I would have to see it from a lower power.
Q. I'm going to come around just for a second because it's difficult to describe these things on the record.
-- OFF THE RECORD DISCUSSION --

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BY MR. COMBS:
Q. Dr. Iakovlev, I came around and marked an A and a B on the top of the photograph?
A. There are other areas also representing B type of changes, artifact.
Q. Okay. So here was my question. Are the areas that are denoted as A and B now on DH5, do those represent normal tissue?
MR. ANDERSON: Objection. Asked and answered; go ahead.
THE WITNESS: So because I can see the B areas, which are definite artifact; I cannot give you an answer regarding A at this magnification.
BY MR. COMBS:
Q. All right. Dr. Iakovlev, is it your opinion that the photographs that are designated DH2 through 5 represent scar plate?
MR. ANDERSON: Objection. Go ahead.
THE WITNESS: Okay. So there's a combination, DH2 through DH5. And DH6 and DH7, DH8, all of these photographs capture at least part of this scar plate.
MR. ANDERSON: All the way through DH9?

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THE WITNESS: Yes. Including DH9.
BY MR. COMBS:
Q. And Dr. Iakovlev, we earlier marked as Exhibit 2 the pathologist's report prepared by the treating pathologist in this case, didn't we?
A. Yes.
Q. And Dr. Small, the treating pathologist in this case, performed an examination with a light microscope just like you did, didn't he?
A. Yes, he did.
Q. And Dr. Small did not note that there was scar plate in any portion of this tissue sample, did he?
A. He didn't use the word of scar plate.
Q. In fact, he described it as benign connective tissue and skeletal muscle, didn't he?
A. That is correct. Fibrous tissue, scar tissue are all benign tissue. And connective tissue includes scar, bone and many other, so it's more of a very broad description.
Q. And so Dr. Small's description was

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benign connective tissue and skeletal muscle, and not scar plate, wasn't it?
MR. ANDERSON: Objection to the form. Go ahead.
THE WITNESS: Again, I don't know exactly what he meant describing connective tissue there. Different types of connective tissue.
BY MR. COMBS:
Q. The word "scar plate" does not appear at any point in Exhibit 2, does it?
A. It does not appear there.
Q. Dr. Iakovlev, I want to ask you now some questions about the photographs where you label and define nerves?
A. Yes.
Q. Let's go to DH6. And you have several nerves pointed out on the bottom of that picture.
So here is the first thing I want to ask you: Do those nerves that you've identified show any signs of degeneration?
A. No.
Q. Distortion?
A. It's hard to say. They are

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somewhat tortuous. Is it normal? Sometimes nerves can do that.
I would -- I wouldn't rule out if we cut really deep, like millimeter or half a millimeter deep, that this nerve would hit the fiber here and become distorted.
Q. You cannot testify to a reasonable degree of medical certainty that that nerve is distorted, can you?
A. Not at this level, but if I cut deeper sections, I may.
Q. Based upon the slides that you've prepared that are included within your report, you have not made that finding, have you?
A. No, but I reserve the right to supplement it if I find new features.
Q. Dr. Iakovlev, there are no features that you would say diagnose a traumatic neuroma, are there?
A. Again, at this level, I cannot demonstrate that. But I don't know what's deeper in the block.
Q. Dr. Iakovlev, I want to ask you now about DH7.

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A. Yes.
Q. Now what is your opinion regarding DH7?
MR. ANDERSON: Objection to form. Go ahead.
THE WITNESS: There are quite sizeable nerves there. They are in the scar plate right beside the mesh fibers. This is not normal situation. Normal nerves are in normal tissue. Having a large nerve in the scar plate indicates it's entrapment in the scar tissue.
So if we think about it, we just went through the images of scar plate being connected to the striated muscle. So every time this striated muscle would contract, it would move the entire scar plate or apply traction, at least, and then the traction would transfer to these nerves, which are coming from normal tissue.
So essentially the nerves are attached, firmly immobilized in the scar plate, and then the scar plate is being tugged. This can provide direct irritation to the nerves. So that's one component of this finding.
Second component is that as we see that

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there are some branches, we know that the tissue within the scar plate and around it is innervated so it can sense pain.

Although it is expected finding that it would sense pain, the image just reminds us one more time that it is a live tissue; it's not dead tissue. And if we have any distortion, any degree of distortion, it will hurt.

It's like pinching the skin. If you pinch skin, it hurts, and the same thing happens deep under the mucosa. If there is any distortion, any pulling, it will hurt.

BY MR. COMBS:

Q. Are there any nerve receptors identified in DH7?

A. No, I did not try to identify them.

Q. Dr. Iakovlev, are the nerves that you point to on DH7, would those be nerves that grew into the mesh or that would have been in place prior to the mesh's insertion?

A. I would -- my estimate is that these nerves were secondarily involved because these are quite sizeable nerves and --

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But again, it may be some larger nerves can grow through the -- depends on what is damaged during the surgery. If larger nerves are damaged during the surgery, they will attempt to reinnervate their targets.

Q. Dr. Iakovlev, do any of the nerves in DH7 show signs of degeneration?

A. No, I cannot appreciate that.

Q. Distortion?

A. No.

Q. Any evidence that you would point to to say that they exhibited the features of a traumatic neuroma?

A. No.

Q. Dr. Iakovlev, how far are those nerves away from the mesh in the left-hand picture of DH7?

A. You mean mesh fibers?

Q. Yes, sir.

A. Because the mesh is a large structure, it has large pores and folds, so these nerves can still be in the, within the mesh.

Q. How far are they away from the mesh fiber that's identified at DH7?

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A. So the closest mesh fiber is around 400, 450 microns, just around half a millimeter.

Q. Are there any vessels associated with the nerve in DH7?

A. There are small capillaries, not directly -- well, there's something here. Small capillaries, much smaller than the nerve itself.

Q. Dr. Iakovlev, there's a blue line in between the fiber and the mesh; do you see that? This line right here?

A. Yes, I do.

Q. What is that?

A. That's an artifact.

Q. And just for the jury's benefit; what do you mean when you say it's an artifact?

A. There's a little fold in the tissue. When it was cut, that little, the thin slice of the tissue wrinkled slightly so it is a wrinkle in the slice of the tissue.

Q. Dr. Iakovlev, I want to ask you about DH8 now. What is your opinion regarding DH8?

A. This is a similar feature, and I used the same S100 stain, which highlights

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myelinated nerve fibers and myelinated nerves.

There's a scar plate, as we discussed earlier, around the mesh fibers, and within the scar plate there is some inflammation. And the scar plate is formed by the scar tissue which is bridging within the mesh pores and encapsulating the mesh.

And then there are two nerves, at least two nerves, maybe more -- at least I can see it from this power.

Q. Can you circle the two nerves?

A. So this is one nerve and I think there are three -- again, from this power it's hard to see. Maybe there are three. If these are cross-sections these will be three. I cannot say exactly what's going on in lower --

Q. Just so the record will be clear, when you're saying you can't say exactly what's going on, you're talking about the bottom one that you circled?

A. B, and the more clear appearance is in A.

Q. Okay.

A. Because A is the longitudinally

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section nerve. And B appears to be cross-section of nerves. But I cannot say for sure from this power.

Now, this nerve has some clearing, but I think it's not nerve degeneration; it may or may not be.

However, overall, it seems to be healthy nerve, or at least functional nerve, and what is abnormal is its location in the scar plate. And as I described before, by location in the scar, it is entrapped in the scar.

And it can be deformed within the scar plate. It can be pulled and distorted within the scar plate within contraction due to contraction of the scar plate, due to contraction of the attached muscles.

And, as previously, the nerve indicates innervation in the scar plate and around it providing several mechanisms for pain development in these ladies.

Q. Dr. Iakovlev, for any of the nerves that you see in DH8, can you say that there are features that show degeneration?

A. As I said, the one which is

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circled A, I see some clearing, but I would need the slide just to have a look. Because degeneration of the nerves, especially when they get trapped, it's a focal, it's a so-called Renaut body.

Focal area of degeneration, they are reported to be associated with a nerve entrapment or chronic trauma of nerves.

Q. Can you say to a reasonable degree of medical certainty that there is any degeneration depicted in the photograph on DH8?

A. That wasn't my purpose. If I was expecting your question, I would examine it, and prepare that answer. But now I would need a slide and examine it in the microscope to give you an answer.

Q. Any of the nerves in DH8 distorted?

A. This nerve appears to have some curve to it.

Q. Is that A or B?

A. A.

Q. Thank you.

A. I cannot tell you if it's a real

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distortion by the mesh or just the shape of it again. Again, I would need a slide and maybe correlate it with H&E to tell you definitively.

Q. Are there any features in DH8 that you will point to to say are indicative that there is a traumatic neuroma?

A. No.

Q. DH9. Does that depict a nerve?

A. Three nerves.

Q. And can you circle the three nerves?

A. (Witness complies).

Q. And Dr. Iakovlev, are there vessels in that picture?

A. Yes, there are.

Q. And can you take maybe this green highlighter and highlight any vessels that you see?

A. (Witness complies).

Q. Any others?

A. Other small capillaries here and there.

Q. Thank you. Do those nerves show any indication that they have degenerated?

A. I don't think so. There's some

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clearing, but I think it's some capillary running across it.

Q. Are those nerves distorted?

A. Not that I can appreciate.

Q. Do those nerves show any evidence that they are a traumatic neuroma?

A. No.

Q. Dr. Iakovlev, I want to ask you collectively for the --

A. Just thinking, one more time. I would need really a slide to tell you exactly if there is any degeneration or not. There is some clearing. Again, I would -- cannot give you definitive answer just by picture.

Q. When you say there is some clearing; which nerve are you pointing to?

A. This large oblong.

Q. The long one on the right-hand side?

A. Yes. If it was my purpose to identify if there is degeneration or no degeneration, I would cut deeper and investigate it, but it has no bearing on my opinions, because we know it's already in scar tissue.

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So if it is degeneration or not, it just shows the effect of it. But, I mean, we know it's already an abnormal location.

Q. Collectively I want to ask you about the photographs that are from DH6 to DH9.

Did you consult with a neuropathologist for any aspect of your opinions related to the nerves that are depicted in DH6 to DH9?

MR. ANDERSON: We will stipulate for this and all other Wave One claimants that Dr. Iakovlev did not see the need to, nor did he, consult with a neuropathologist.

BY MR. COMBS:

Q. In the photographs at DH6 through DH9, you do not appreciate any nerve ganglia, do you?

A. No.

Q. And I believe I asked you this, but just in case I didn't. For none of the slides related to the specimen, did you stain them with PGP9.5 or neurofilament stain?

A. That is correct.

Q. As a result of that, are you unable to appreciate whether there are any nerve

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receptors in any of the slides?

A. Wasn't my intention, so I was not looking for them. Not that I was not able, but just didn't do it.

Q. Dr. Iakovlev, do you hold the opinion that any aspect of Ms. Hankins' mesh roped or curled?

A. (Witness reviews document).

The tissue came in pieces so I don't think I can assess it for curling or deformation.

Q. Dr. Iakovlev, I'm going to ask you just, I think, a very short series of questions regarding the photographs that you have labeled DH10a through 12c.

Are those the ones that you're going to use to present your testimony related to what you claim was degradation of the mesh?

A. That's correct.

Q. And would your opinions be the same as they have been in -- when you've been deposed in your general depositions regarding degradation issues?

A. That's correct.

Q. I do have one question. Let's go

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to, for example, DH10; do you see where you have the degradation layer identified on the right-hand photograph?

A. This one?

Q. Yes, sir. And I just wanted to ask you how thick you believe that degradation layer is?

A. Again, this is a really rough estimate without a micrometer or without any reference points. Just by looking at it, it's at least 4 microns, maybe 5. Maybe even thicker. Maybe 6.

Q. Okay. Somewhere between 4 to 6 microns?

A. Probably around 4 microns.

Q. All right. Thank you?

MR. COMBS: Let's take a break for a minute.

-- RECESS AT 6:39 --

-- UPON RESUMING AT 6:47 --

BY MR. COMBS:

Q. Dr. Iakovlev, I want to ask you questions now about your clinico-pathological correlation, and let's start with the urinary

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symptoms. What are the urinary symptoms that you believe are related to Ms. Hankins' mesh implant?

A. So after the mesh placement in August 2007, she presented with urinary problems in March of 2010, which were described:

> "She presents today secondary to difficulty urinating which has been going on since her hysterectomy in 2007 or 2008, at which time she also underwent sling placement."

And then it continues on, and then it says:

> "She does not have any stress incontinence. She has a severe sense of urgency."

So her incontinence type changed. Before procedure she had stress incontinence. And after the procedure, she has urinary obstruction and urge.

Q. And what is the mechanism by which you think that Ms. Hankins developed urinary obstruction?

A. Urinary obstruction is caused in case of implantable meshes.

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MR. ANDERSON: We're talking about in the case of her.
THE WITNESS: Yes, in the case of Ms. Hankins, was caused by the scar contraction within the sling, which was placed in the body of Ms. Hankins.
And, as we know, scar contracts during maturation, as we all see in some burn victims, those who have some larger scars, and it contracts and it tightens the sling.
And the sling obstructs the urethra, overtightens over time. Usually it takes several months or up to a year. In this case, presentation was a year and a half, or no, more than that. Or two and a half years.
BY MR. COMBS:
Q. I'm sorry, I did not mean to interrupt you.
A. So it's more than two years.
Then there's investigation further on after that visit in 2010. Dyspareunia and obstructive pattern. Again, obstructive pattern, that's where the cystoscopy was done and she has an incidental finding of superficial carcinoma.

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MR. ANDERSON: Are you finished?
THE WITNESS: Yes.
BY MR. COMBS:
Q. You believe that Ms. Hankins' urinary obstruction was caused by scar contraction related to her sling; is that correct?
A. That is correct.
Q. And you stated that her stress urinary incontinence after she had an implant shifted from stress urinary incontinence to urge incontinence?
A. That is correct.
Q. And it is your belief that Ms. Hankins' obstructive voiding started approximately a year after her mesh was implanted; is that correct?
A. No, I don't know exact timing in between these two entries. Sometime by 2010 she already had developed obstructive pattern.
Q. For the mechanism to be scar contraction it would have to be sometime from several months after the implant to a year after the implant; wouldn't it?
MR. ANDERSON: Objection to the form.

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Go ahead.
THE WITNESS: It can be several weeks after implantation. Because scar starts contracting pretty much after first month, after surgery.
And then it can continue on and then can become tighter and tighter and tighter with time. But the beginning of it can start as early as one month after the placement surgery.
BY MR. COMBS:
Q. Did you review any records that indicated Ms. Hankins had urinary obstruction in less than a month after her surgery?
A. I don't recall these records.
Q. If there are records that Ms. Hankins had urinary obstruction in less than a month after her surgery, would you agree with me that that would point to an issue of the sling being placed too tight rather than scar contraction?
A. That would be one scenario. However, it would have to be a specific situation which would have to be worked up, clinically investigated.

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Q. That would be in somebody else's domain, not yours?
A. That's correct. I mean, correctness of placement, the timing of urinary obstruction. Some obstruction can happen right after surgery, but not to the -- not due to the mesh. Due to medications, due to swelling from surgery or something else. We cannot disregard those factors as well.
Q. If Ms. Hankins' obstructive voiding started prior to one month, that could not have been due to the mechanism of scar contraction, could it?
MR. ANDERSON: Objection. Asked and answered. Go ahead, one more time.
THE WITNESS: There would be minimal contribution of scar contraction. It will slowly get more and more and more, and once we get to a month there will be more contribution, and then it continues on.
But the immediate postoperative period may have other causes for urinary obstruction.
BY MR. COMBS:
Q. Those other causes would be

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outside of your area of expertise, wouldn't they?
A. Unless I have a specimen and I see a tumor or something else, then I can tell you that.
Q. But you do not have any specimens from the period of August 29, 2007, to September 29, 2007, do you?
A. That's correct.
Q. Dr. Iakovlev, you said that you believe Ms. Hankins' urinary incontinence changed from being stress urinary incontinence to urge incontinence after her surgery.
As part of your differential diagnosis to draw that conclusion, did you review to see whether Ms. Hankins had urge incontinence prior to her implant?
MR. ANDERSON: Objection to the form of that question.
THE WITNESS: As with previous cases, I remind you that I do not conduct clinical differential diagnosis. I take conclusions which are already done by the treating physicians.
And it's clear to me in the records that the obstructive pattern and the urge

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incontinence were attributed to the sling, and that's why she had sling excision.
BY MR. COMBS:
Q. Dr. Iakovlev, I realize that you're not a urologist, but do you know whether the sling is intended to treat urge incontinence?
A. Not urge. Sling is intended to treat stress incontinence.
Q. I've got a group of records I'm going to collectively mark as Hankins 4.
MR. COMBS: Ben, can you share these with Dr. Iakovlev. I might have a second set, but let me look and see.
MR. ANDERSON: Sure, that's okay, I can do it.
EXHIBIT NO. 4: Compilation of Clinical Examination Notes (five).
MR. COMBS: I do have a second set.
BY MR. COMBS:
Q. Dr. Iakovlev, you can review these or I can just start asking -- I'm only going to ask you about certain pages of them.
A. (Witness reviews document). Um-hmm.

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Q. So let's start, the second page which is dated July 19, 2004, and I'm going to ask you about this line starting right here. Second page, the Bates number on it is 246.
A. Okay.
Q. Do you see the line where it says:
"USI with cough, sneeze. Also urgency/urge incontinence. Daily loss of urine. Wears panty shield."
Do you see that?
A. I do.
Q. Do you see down at the bottom:
"Diagnosis: USI, urge/urge incontinence/cystocele."
A. I do.
Q. Is the fact that Ms. Hankins was diagnosed with urge incontinence in 2004 a fact that you factored into your differential diagnosis that her incontinence changed from stress urinary incontinence to urge incontinence?
A. I considered all records, as I said. But I'll leave this detail, specific of development of this to clinical colleagues. It's not area of my expertise.

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Q. But is the fact that Ms. Hankins had urge incontinence in 2004 a fact that you considered in your determination that her incontinence changed from stress incontinence to urge incontinence after the device was implanted?
MR. ANDERSON: Objection. Asked and answered. It's the exact same question you asked except you put the word "but" in front of it.
MR. COMBS: Yes, I was trying, because I didn't get an answer to the first one.
MR. ANDERSON: Yes, you did. He said he considered all records.
BY MR. COMBS:
Q. Okay. So you did consider this record?
A. I did consider. It's 2004, and I don't know exactly why there is urge. Maybe there's a UTI, and then there's a gap. I mean, there's so many variables, I have to leave it to clinical expert.
Q. Let me ask you now about the page that's Bates numbered at the bottom 95. I think it's the fourth page.
MR. ANDERSON: Which one?

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BY MR. COMBS:
Q. The Bates number on it is 95. I believe it's the fourth page.
A. Yes.
Q. Now, Dr. Iakovlev, do you see about the seventh or eighth line down where it says:
"Also complains of urge incontinence - did well on Oxytrol in past."
A. The handwriting, oh, it's difficult. Yeah, I can see at least one word, "urge."
Q. Well, "CO" in medical records stands for "complains of" doesn't it?
A. Chief complaint --
Q. Okay, chief complaint --
A. No, yes. "Complains of," sorry, okay.
Q. All right. And does this record indicate that Ms. Hankins was complaining of urge incontinence on -- in April of 2007 as well?
A. Yes, it does.
Q. Does it reflect that she, that the

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record says, "did well on Oxytrol in past," close quote?
A. Yeah, I mean if it's Oxytrol. I mean, I cannot read that writing.
Q. All right. Did you consider in your differential diagnosis that Ms. Hankins' incontinence changed from stress urinary incontinence to urge incontinence after the implant, did you consider the fact that she had urge incontinence in April of 2007?
A. As I said, I considered all the records, but I'm not a urogynecologist. I will leave these symptoms to urogynecologist. I can see clearly that it states that there is urge after TVT-O. How much of it is -- sorry, TVT or TVT-O?
Q. TVT in this case.
A. How much of it is due to TVT or preexisting condition would have to be clinical expert. What I can tell you is that there was a reason for urge incontinence as a part of mesh-related complications.
If there were two types of urge incontinence, or two causes at the same time, that's not my area of expertise.

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Q. You can't testify that the mesh was, in fact, the cause of her urge incontinence, can you?
MR. ANDERSON: Objection. Asked and answered.
THE WITNESS: Not all of the urge symptoms.
BY MR. COMBS:
Q. Well, you can't testify that they were the cause of any of the urge symptoms, can you? There were two possible causes you've said, preexisting and the mesh?
MR. ANDERSON: Objection. Mischaracterizes his testimony and asked and answered. You can answer one more time because we're not going to mischaracterize what he said.
THE WITNESS: Because those two causes could coexist together after the implantation.
BY MR. COMBS:
Q. You have never looked at any voiding diaries for Ms. Hankins, have you?
A. I didn't.
Q. You do not know whether her urge symptoms were better or worse after the implant, do

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you?
A. I don't.
Q. You do not know whether she currently exhibits urge incontinence, do you?
A. I don't.
Q. You would not be able to tell us the extent of her urge incontinence at any time during her treatment of 2004 to the present, would you?
A. I wouldn't.
Q. Let's talk some more about pain and dyspareunia.
Dr. Iakovlev, is it your opinion in this case that Ms. Hankins' pain and dyspareunia was caused by the TVT sling?
A. (Witness reviews document).
MR. COMBS: Let's go off the record.
-- OFF THE RECORD DISCUSSION --
THE WITNESS: The record after the mesh placement in March of 2010 says: "Sex is uncomfortable." That's the first entry.
Then, next entry, April 2010:
"History given of dyspareunia and an obstructive pattern."

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And:

"No evidence of interstitial cystitis."

But at that point the attention is completely focused on the carcinomas, or there's a gap of attention to the -- and then we go to June 2010.

After the superficial carcinoma is treated, the attention is again refocused to the mesh problems. Dyspareunia is listed together with obstructive voiding here.

Now, continuing on. August 2011, she does have obstructive voiding, dyspareunia and symptomatic rectocele and cystocele.

So it seems like after the cancer was treated, and when the attention was refocused, Ms. Hankins was ready for removal of the sling.

So her symptoms which were attributed to the sling were high enough to trigger the excision, or at least she was convinced that she needs sling excision.

BY MR. COMBS:

Q. And do you believe that this sling was excised?

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A. Sorry, I didn't finish.

Now, when this problem started being worked up, the examination was, the mesh was palpable, so it was tight enough to be palpable, which corresponds with pain, dyspareunia and obstructive pattern.

When it is tightened it compresses the urethra and produced obstructive pattern. And then further down, she's found to have an erosion through the vaginal mucosa. So on top of the tight band, tight mesh, she has mucosal erosion.

Now, when the mesh was being dissected, not just erosion into the vagina was found, but the sling was so tight that it was almost eroding into the urethra, and the urethra had to be freed completely from scar tissue.

Q. Are you finished with that answer?

MR. ANDERSON: He's still looking.

THE WITNESS: I'm still looking, give me one second.

(Witness reviews document).

MR. COMBS: Let's go off the record again.

THE WITNESS: Then the attention then

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again refocused here. So just putting all these records together, I can see there was dyspareunia reported after mesh placement together with obstructive pattern.

There was evidence that the sling was overtightened so it was compressing on the tissue. And then mucosal erosion was discovered further -- later on.

And during the surgery, it was found that there was a tight sling which was almost eroding into the urethra.

BY MR. COMBS:

Q. Dr. Iakovlev, you haven't read Dr. Dunn, the explantor's deposition, have you?

A. No.

Q. You do not know whether Dr. Dunn concluded that the sling was a cause of Ms. Hankins' dyspareunia in 2010, do you?

MR. ANDERSON: Again, he has not reviewed any depositions, as we stated earlier in this deposition. So if he hadn't read it, he wouldn't know what he said.

BY MR. COMBS:

Q. You do not know whether Dr. Dunn

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concluded the sling was a cause of Ms. Hankins' dyspareunia in 2010; do you?

A. What do you mean? Which doctor?

Q. Dr. Dunn, the explantor?

A. Well, I mean, he had a reason to explant it.

Q. Yeah. Do you know what Dr. Dunn's reason was for explanting the sling?

A. He describes tight mesh, which is eroded and almost eroded in the urethra.

Q. Do you know when Dr. Dunn made the decision to explant the mesh rather than lyse the mesh?

A. What do you mean "lyse"?

Q. Cut the mesh.

A. Transect?

Q. Yes.

MR. ANDERSON: The question is when he decided?

MR. COMBS: Do you know?

BY MR. COMBS:

Q. Do you know when he decided. It's actually a "she." Do you know when she decided?

A. No, I don't.

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EXHIBIT NO. 5: Urogynecologic Follow-Up Report dated August 18, 2011.
BY MR. COMBS:
Q. Dr. Iakovlev, let me hand you what's been marked as Exhibit 5, and let's talk about that some.
On August 18, 2011, Ms. Hankins had multiple factors that contributed to her dyspareunia, didn't she?
A. Yes. Could contribute to her dyspareunia.
Q. That did contribute to her dyspareunia, didn't they?
MR. ANDERSON: Well, objection. Asked and answered.
BY MR. COMBS:
Q. Okay. Well, let's go through.
Do you know whether Ms. Hankins' symptomatic rectocele and cystocele contributed to her dyspareunia?
A. This would be more for clinical experts. Cystocele, rectocele, atrophic vaginitis -- I mean, my understanding is atrophic vaginitis would be a more significant factor rather than

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cystocele and rectocele, but I would have to defer you to clinical experts.
Q. And you see that in Ms. Hankins' examination she was found to have cystocele to the introitus, as well as a rectocele; what does that mean?
MR. ANDERSON: Objection. He stated that this would have to be deferred to a urogyn.
BY MR. COMBS:
Q. Are you able to tell the jury what it means to have cystocele to the introitus?
A. It's not my area of expertise. It's -- cystocele and rectocele it describes a degree of cystocele and rectocele.
Q. "To the introitus" -- would that mean the cystocele had fallen to the vaginal opening?
A. Fallen or is visible, again, it's not my area of expertise. I'm afraid I cannot give a correct and detailed answer.
Q. Now, Dr. Dunn found that Ms. Hankins had decreased vaginal tone, didn't she?
A. Where exactly?
Q. It's on the pelvic exam between

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"Physical Examination" and "Impression," right there.
A. Yeah, I can see "decreased tone."
Q. Do you know whether the decreased tone contributed to Ms. Hankins' dyspareunia?
MR. ANDERSON: Again, he has said he has to defer to a urogynecologist 12 times. Do you want him to say it for 13?
THE WITNESS: Yes, that's exactly what I would do. I would say that.
MR. ANDERSON: Thirteen, good.
BY MR. COMBS:
Q. Do you know whether Ms. Hankins' atrophic vaginitis contributed to her dyspareunia?
MR. ANDERSON: Objection. Go for 14.
THE WITNESS: It could contribute, but it's easily treatable condition. As I said, all women have it. It doesn't mean that all women cannot be treated.
BY MR. COMBS:
Q. And do you know whether Ms. Hankins was, in fact, treated for atrophic vaginitis through a prescription for estrogen?
A. Again, I would have to defer this.

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When I see a sling and foreign body tight enough to almost invading into the urethra and then invading into the vaginal mucosa and being palpable as tight, I think this is a factor which is much stronger than just atrophic vaginitis.
But, again, I see that it was clearly abnormal to have a ridge of tight, scarred mesh pressing against the urethra, distorting the tissues around and eroding through the vaginal mucosa, and I can relate it with histological findings.
Q. Okay. I believe my question was, was Ms. Hankins' atrophic vaginitis treated through a prescription for estrogen?
A. It could be. As I said, I mean, I would have to defer you to clinical colleagues. I mean, I see it all the time. It's being treated and...
Q. Do you know whether Ms. Hankins' cystocele and rectocele were treated by performing a pelvic organ prolapse repair using a porcine graft?
A. Not at the time of TVT-O placement.

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Q. No, that's correct. I'm talking about during the 2011 surgery.
I'm talking about the November 14, 2011, surgery.
A. Yes, I see there was anterior and posterior repair at the same time.
Q. You do not hold any opinion that that posterior and anterior repair were as a result of the sling in this case, do you?
A. We are talking about symptoms which predate the anterior and posterior repair, are we?
Q. My question is, do you hold any opinion in this case that Ms. Hankins' vaginal sling played any role in her prolapse that was surgically treated in November of 2011?
MR. ANDERSON: Objection. Again, he's not a urogyn. Don't answer urogyn questions.
THE WITNESS: I frankly don't understand the question.
BY MR. COMBS:
Q. Okay. You don't understand that question?
A. I mean sling is -- are you asking

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that if I have opinion that sling caused the cystocele and rectocele?
Q. Yes.
A. No, I don't think so. At least, not to my understanding. But you're better off asking a urogyn.
MR. ANDERSON: Thank you.
BY MR. COMBS:
Q. Dr. Iakovlev, do you know whether Ms. Hankins currently has dyspareunia?
A. I don't.
Q. Do you know whether she had dyspareunia at any point after the November 2011 procedure?
A. Could you repeat the question. Sorry.
Q. Do you know whether Ms. Hankins had dyspareunia at any point after the 2011 surgical procedure?
MR. ANDERSON: Where are you looking now? What page of your report?
THE WITNESS: Yes, there were some symptoms of dyspareunia after that procedure.

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BY MR. COMBS:
Q. When were those symptoms?
A. There was vaginal pain with initial and deep penetration.
MR. ANDERSON: He said when.
THE WITNESS: Sorry, February 2012.
BY MR. COMBS:
Q. And any other reports of dyspareunia after 2012?
A. (Witness reviews document).
So she gets this burning pain one month after the surgery, so it's pretty much immediate postoperative period. (Witness reviews document).
Then, let me focus. I don't see it anymore. There was some pain in the immediate postoperative period, but then...
Q. Dr. Iakovlev, as part of your differential diagnosis regarding whether Ms. Hankins' pain and urge incontinence were caused by the mesh implant, did you consider the fact that she had had multiple cystoscopies?
MR. ANDERSON: Objection to his differential. Go ahead.
THE WITNESS: Let me understand the

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question.
So if her pain and dyspareunia and urinary --
BY MR. COMBS:
Q. -- or urge incontinence?
A. -- urge incontinence were caused by --
Q. Could be caused by cystoscopy?
A. -- cystoscopies?
MR. ANDERSON: Objection to the form. Go ahead.
THE WITNESS: Yeah, this is question definitely for urogynecologist or urologist.
BY MR. COMBS:
Q. Do you know whether a cystoscopy can cause urge incontinence?
MR. ANDERSON: Objection. Goes beyond his expertise; he's not a urogynecologist. Go ahead.
BY MR. COMBS:
Q. Do you know whether a cystoscopy can cause pain?
MR. ANDERSON: Same objection, same instruction.

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THE WITNESS: That's definitely beyond my expertise.
BY MR. COMBS:
Q. Dr. Iakovlev, do you know whether Ms. Hankins had at least a dozen cystoscopies between April 16, 2010, and June 29, 2015?
MR. ANDERSON: Do you want him just to assume that that's in the record, so he doesn't have to spend time counting them?
BY MR. COMBS:
Q. I'll represent to you that she had a dozen cystoscopies, approximately a dozen cystoscopies during that time period.
Did you factor that into your differential diagnosis regarding the cause of her pain and urge incontinence?
MR. ANDERSON: Same objection regarding his differential diagnosis. Same objection regarding outside the scope.
If you feel comfortable answering that, given my instructions.
THE WITNESS: Yeah, this is the same answer. It's not question for me.

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BY MR. COMBS:
Q. Dr. Iakovlev, do you know whether Ms. Hankins was treated for her bladder cancer?
A. Yes, she was.
Q. And was one of the treatments that she received for her bladder cancer BCG therapy?
A. Later on, at the very end, yes.
Q. Do you know whether urge incontinence is a risk of BCG?
A. When it is administered, yes. It's a significant factor. But it happened only in 2015.
MR. COMBS: Dr. Iakovlev, I don't have any more questions at this time.
CROSS-EXAMINATION BY MR. ANDERSON:
Q. Dr. Iakovlev, you were asked whether or not half the specimen that you were able to look at went to Defense; do you recall that?
A. I do.
Q. Have you ever had an opportunity to look at the slides that were taken from that, if any were created by the Defense. Have you had an opportunity to look at those?
MR. COMBS: Objection, because I didn't

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ask that question.
BY MR. ANDERSON:
Q. Okay. In your report it says half the specimen was sent to the Defense. Do you recall that in your report?
A. I do.
Q. Have you ever had an opportunity to look at any slides that may have been created by the Defense from those half, that half of the specimen?
A. No.
Q. Would you like an opportunity to be able to look at those in order to determine whether or not you have any supplemental opinions based upon being able to resume a full 50 percent of the slides that would be with the Defense right now?
A. I do.
MR. ANDERSON: We will reserve our right to supplement his opinions based upon counsel sending this back to us, and we have a stipulation that was on the record as of the last deposition that as soon as these reports are handed in, which should be March 16th, that we will have -- that Dr.

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Iakovlev will have returned to him, his half of the specimens, plus whatever slides the Defense experts create.
MR. COMBS: And I can't speak to that since I wasn't here for the last deposition, but whatever the record reflects, it reflects.
MR. ANDERSON: You wouldn't have any objection providing those per PTO-190, would you?
MR. COMBS: I'm not sure that's what PTO-190 says. But in any event, I'm not the person to ask that question of. And if that's what the stipulation placed on the record was, that's fine.
MR. ANDERSON: Okay, great.
BY MR. ANDERSON:
Q. So you were asked a number of questions about whether or not you counted nerves, found any traumatic neuromas and found any neural ganglia involvement in any of your slides; do you recall that?
A. I do.
Q. Do you remember the part of your testimony and the part of your report where you showed numerous slides where nerves were entrapped in scar plate?

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A. I do.
Q. Do you need to be able to either count the nerves, look for -- find traumatic neuromas or find neural ganglia involvement in order to express your opinions as to whether or not Ms. Hankins experienced mesh-related nerve pain due to nerve entrapment and scar?
A. I don't have to see those.
Q. Okay. And why is that?
A. Finding nerve in scar tissue is already abnormal. Even a single nerve in scar tissue is already abnormal. How many nerves do you need to feel pain? I mean, like a needle prick. I mean, how big is that needle prick?
Q. You were asked a question as to whether or not there was some degree of hardening, shrinking, or change in shape of specimens as a result of formalin; do you recall that?
A. I do.
Q. Was there any significant degree of hardening, shrinking, or changing shape of the sample for Ms. Hankins that prevented you from being able to offer the opinions that you did, based upon your review of the clinical records and

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your correlation of those with your pathological findings on all of the slides that we've looked at with counsel and that are in your report?
A. No, I mean, just consider this. Entire world functions through the same procedures. All cancers, all diseases are diagnosed using exactly the same procedures, which shrink to a degree -- tissue. I mean, medicine functions based on the same procedures.
Q. The same procedures being?
A. Being used every day for millions of patients, formalin fixation, dehydration, slicing tissue by microtome. That's how people are treated, and that's how people are diagnosed.
Q. So in your opinion, that's not something that's unique to the mesh litigation; that's something that's used millions of times around the world every day?
A. Yes, and it's being validated. We know that our medicine is functioning, and functioning better and better every year.
Q. You were asked whether you used myeloperoxidase, something called PGP9.5 or neurofilament, all the types of staining on your

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slides. Do you remember those questions?
A. Yes.
Q. Do you need myeloperoxidase, PGP9.5 or neurofilament staining in order to express the opinions you did based upon the slides in your report indicating your opinions with the correlation between the clinical findings and your findings on the slides?
A. No, I don't.
Q. Were you able to use the H&E and the S100 to be able to come to your opinions without needing any of these additional stainings on all of these slides?
A. Yes.
Q. You were asked some questions about erosion, and whether that was due to migration or any of the tissues. Do you remember all that?
A. I do.
Q. Do you remember your testimony about all women as they age will have some sort of age-related atrophy of their tissue?
A. Yes.
Q. Do all human beings have some form

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of age-related atrophy of their tissue as they get older?
A. Yes.
Q. Despite this, whether or not it was the thinning or the migration, do you have an opinion to a reasonable degree of medical certainty, based upon your background, training, experience, your review of over 200 explanted meshes, your publications in this area, your review of the medical records, and your review of the slides in this case as to whether or not the erosions that were suffered by Ms. Hankins were due to the mesh?
Do you have any question as to whether or not -- do you have an opinion, first of all, whether it was related to the mesh?
A. I have an opinion.
Q. What is that opinion?
A. My opinion is these changes were related to mesh.
Q. As set forth in your report and your testimony here today?
A. Yes.
Q. Okay. You were asked questions as

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to whether or not the treating physicians found mesh-related infection and whether any cultures were taken; do you remember that?

A. I do.

Q. Do you know if any of the treating physicians ever did histology or looked at her mesh under a microscope?

A. They didn't.

Q. Okay. And you said erosion, when there's erosion the infection -- and your words were, "it's a given." Can you explain to the jury what you mean by that?

A. If there is a breakdown of either skin or mucosa it's exposed to environment. And environment always has bacteria, so there will be infection. That's why we put Band-Aids on cuts, so they don't get infected, so they heal faster.

Q. Are you familiar with the terms a "systemic infection" versus a "localized mesh-related infection"?

A. -- yes.

Q. Please explain to the jury the difference between if someone has a systemic infection versus a localized infection?

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A. Localized infection is where the infection is just in the wound. I mean, if we have cut on skin and then there is redness around it, then it heals over. So that is self-limited infection right there, or localized infection.

There's a foreign body, that will persist. So there is continuous chronic infection in the area.

But if we're talking about systemic infection, it is infection which travels through bloodstream and can affect the entire body. That infection would need antibiotics for treatment; where the localized infection needs to be treated locally. In the case of foreign bodies, it means treatment is excision of the foreign body.

Q. Is that what happened in this case?

A. That's exactly what happened.

Q. You were asked some questions about your figures in DH3 and DH4 where you were discussing the significance of the scar plate anchoring and the scar and striated muscle in Ms. Hankins' slides; do you recall that?

A. I do.

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Q. Explain to the jury what the significance to Ms. Hankins was of these findings of scar plate anchoring to the adjacent striated muscle and scarred striated muscle?

A. So when that scar --

MR. ANDERSON: For her, for Ms. Hankins.

THE WITNESS: When scar became so extensive that it involved striated muscle, in Ms. Hankins' body, first of all, it damaged the muscle. The muscle couldn't function the way it was functioning when it was in healthy state.

And then the second important factor is that the scar plate, which was encasing the entire mesh, became connected to the striated muscle.

So with the muscle contraction, you can get tugging and movement of the entire scar plate, or tensioning of it.

BY MR. ANDERSON:

Q. And you were asked some questions about Exhibit 2. That was the path report of the explanted mesh by this Dr. Small. Do you remember that part of your testimony?

A. I do.

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Q. And did Dr. Small do the same thing that you did when you looked at the medical records and looked at the -- and examined the histology in this case?

A. Yes.

Q. Did he also do the same thing that you or other pathologists do every time they get a specimen?

A. Yes. He receives a specimen which is labeled as "eroded mesh."

Q. Is that a clinical finding?

A. That's a clinical finding, clinical description. And then the pathology describes the mesh. Blue mesh is described grossly, and then --

Q. "Described grossly" means? Looked at it?

A. Looked at it without microscope, but just with naked eye. Then he further describes tissue and the tissue is benign connective tissue and skeletal muscle.

Q. What counsel didn't ask you, why did he put the word "benign" there. What is the significance of that in a pathology report?

A. Because the most important thing we are looking for is it benign or malignant.

Q. Benign or malignant?

A. Yes.

Q. In terms of cancer?

A. Cancer. If it is malignancy, it will need completely different treatment. If it is benign, it means that surgeon excised tissue which was causing the symptoms, and at that point there is no further treatment, or at least no cancer-related treatment.

Q. And counsel asked you the question, he said, well, I don't see the word "scar plate" on there. Would you expect Dr. Small to be describing a scar plate when he was looking at this mesh?

A. When you try to decide it's benign or malignant you ignore things like scar plate and other things, because your main concern is malignancy. So the focus here was benign.

See, when the excision occurred in this specific case, the pathologist most likely was informed or could see in the records that there was malignancy. So for us as pathologists, we always

alert -- we are alerted in each case when there is previous malignancy.

So any tissue comes out of a patient where there is history of malignancy, first thing we look for is it malignant or it's benign.

Q. So his focus was more on looking at cancer versus looking at specific details of the mesh and the tissue?

A. That would be secondary. I mean, he wouldn't be paying much attention. His main concern is cancer or not cancer.

Q. Do you know if Dr. Small has ever seen explanted mesh in tissue samples?

A. I don't know.

Q. You were asked a lot more questions about nerves, and we've looked at some of your images on DH6 and DH7. What is the impact to Ms. Hankins of these nerves that are entrapped in the scar plate?

A. So as we talked about it earlier, there are two important factors. When the nerves are seen in the scar tissue, first of all, it's an abnormal location. So nerve can be normal, but being in scar tissue -- it's an abnormal location;

it's an abnormal environment.

It's not normal for nerves to be in the scar tissue; that's how traumatic neuromas are formed. That's how phantom pain is developing. Every time the nerves gets in scar tissue, there is risk for symptoms, other symptoms.

So that would be direct link between this nerve entrapment in the scar tissue and these symptoms in this case, and symptoms of pain.

The second important factor is that indicates that although it's scar tissue, it still has innervation. So it would be subject or can experience all just regular pain through pinching and pulling and tightening. Like we pinch our skin, we feel pain. The same thing with that tissue.

Now, if we go through the records, it was clearly tight. The sling was tight. The tissue was tightened. The tissue was compressed. There was a lot of distortion in the area, and all of that could be felt.

Q. Do you need to see nerve degeneration, nerve distortion, traumatic neuromas or nerve ganglia in order to come to the opinions

that a healthy nerve entrapped in scar tissue can lead to pain in patients and, in particular, led to pain in Ms. Hankins?

A. I don't need to see nerve distortion or neuroma. If I see neuroma, it just exacerbates the issue. But otherwise, I don't have to see it.

Q. You were asked a lot of questions about urge incontinence, whether she had it before or after the mesh, when she had it, what degree she had it.

You were asked a lot of questions about biologic grafts for rectocele and cystocele. Are you a urogynecologist?

A. No.

Q. Are those the types of questions that you have to come up with a clinical differential diagnosis in your field of pathology?

A. Yes. I mean, somebody would have to work that part.

Q. Somebody other than you?

A. Somebody other than me, work the differential diagnosis, decide that something needs to be excised because there is a lesion which needs

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to come out, and then send it to me.
And from that point, then I can tell the clinicians what is abnormal in that tissue.
Q. Is that what you do every day in your practice?
A. That is what I do every day in my practice. And that's what happened in Ms. Hankins. The clinical decision at the end of the day was to excise the mesh.
I'm explaining what was abnormal in the mesh, and I'm connecting it was the reasons why it was excised.
MR. ANDERSON: Thanks. No more questions right now.
REDIRECT EXAMINATION BY MR. COMBS:
Q. Dr. Iakovlev, you said in response to Mr. Anderson's question quote, "how many nerves do you need to feel pain"?
In order to feel pain, you got to have nerve receptors involved, don't you?
A. No. You don't have to.
Q. Let's break this down. Can a nerve twig feel pain without a nerve receptor?
A. Yes. It would be phantom pain. I

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mean, those patients will feel pain in the leg which doesn't exist anymore which was amputated. There are no nerve receptors. All traumatic neuromas are actually dead ends of the nerves dangled in scar tissue.
Q. And you did not find any traumatic neuromas in this tissue, did you?
MR. ANDERSON: Objection.
THE WITNESS: I did not see it in dissections; that is correct.
BY MR. COMBS:
Q. And you did not stain this tissue with any stains that would allow you to see nerve receptors, did you?
A. No, I didn't.
Q. How many nerve twigs would need to be involved in order for you to feel pain?
A. Maybe one.
Q. Is that your opinion?
A. That's my opinion. Because how big is the needle prick? How large is it?
Q. Dr. Iakovlev, Ms. Hankins had several ultrasounds.
Did you review any of those ultrasounds

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to determine the degree of contraction of her mesh?
A. I believe you cannot measure by ultrasound.
Q. Did you review any of her ultrasounds?
A. No, how can you? You have to know the preexisting length and then measure it with ultrasound. So it has to be measurement at the time of placement, within first month and then maybe later. I mean, nobody does it.
Q. Dr. Iakovlev, you were asked some questions about Dr. Small. You don't have any idea of his background, do you?
A. No.
Q. You don't know whether he has viewed other pelvic meshes, do you?
A. No.
Q. And Dr. Small made no finding of infection in his report that's marked as Exhibit 2, did he?
A. No.
Q. Made no findings of any nerve involvement in any portion of Ms. Hankins' tissue, did he?

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A. Could you repeat this question?
Q. Dr. Small made no findings of any nerve involvement in any aspect of Ms. Hankins' specimen, did he?
A. I don't know if he looked at nerves at all. There's no comment on nerves anywhere.
Q. And you said that Dr. Small and you did the same thing, didn't you?
A. Yes.
Q. Dr. Iakovlev, prior to Ms. Hankins' mesh erosion, she suffered at least a grade-two prolapse; didn't she?
A. Again, this is clinical question, I don't remember exactly what grade it was. I mean -- I'm not the person to answer that question.
Q. Okay.
MR. COMBS: Thank you. No additional questions.
MR. ANDERSON: Okay.

-- Whereupon the deposition adjourned at 7:52 p.m.

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CERTIFICATE OF REPORTER

CANADA)
PROVINCE OF ONTARIO)

I, Judith M. Caputo, the officer before whom the foregoing deposition was taken, do hereby certify that the witness whose testimony appears in the foregoing deposition was duly sworn by me; that the testimony of said witness was taken by me in shorthand, using Computer Aided Realtime, to the best of my ability and thereafter reduced to written format under my direction; that I am neither counsel for, related to, nor employed by any of the parties to the action in which the deposition was taken, and further that I am not related or any employee of any attorney or counsel employed by the parties thereto, nor financially or otherwise interested in the outcome of the action.

_____
Judith M. Caputo, RPR, CSR, CRR

Commissioner for taking
Oaths in the Province of Ontario

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____
VLADIMIR IAKOVLEV, M.D. DATE

Subscribed and sworn
to before me this
_____ day of _____, 20____.
My commission expires:_____

_____
Notary Public